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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,717	10/23/2001	Andre R. Abad	35718/237005 (5718-118)	5409
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ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			EXAMINER KUBELIK, ANNE R	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,717	ABAD ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-12,17-19,38-40,42-46,48-52 and 54-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,9-12,17-19,38-40,42-46,48-52 and 54-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-3, 9-12, 17-19, 38-46, 48-52 and 54-64 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 1-3, 9-12, 17-19, 38, 42-43,46, 48-49, 52 and 54 remain rejected and claims 55-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:2 and 10, expression cassettes comprising the nucleic acid, plants and seeds comprising a construct comprising the nucleic acid and a method of using it to impact a plant pest, does not reasonably provide enablement for any nucleic acid that has 90% identity to SEQ ID NO:1, that hybridizes to SEQ ID NO:1 or that is antisense to a nucleic acid with 90% identity to SEQ ID NO:1, expression cassettes comprising the nucleic acid, plants and seeds comprising a construct comprising the nucleic acid and a method of using it to impact a plant pest. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 12 March 2003, as applied to claims 1-3, 9-12, 17-19, 38, 41-43,46-49 and 52-54. Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

Applicant urges that guidance is provided as to what sequence alterations may be made by structural parameters (percent identity to SEQ ID NO:1) and on pg 18-20 and 33-38 of the specification (response pg 14).

This is not found persuasive. Pg 18-20 and 33-38 of the specification describe a two truncations of SEQ ID NO:1, suggest inserted trypsin and chymotrypsin digestion sites, and provides general guidance for calculation of homology. The pages also suggest making variants by deleting, substituting or inserting one or more amino acids, but do not provide guidance as to which amino acids to delete, substitute or insert. No guidance is provided for making nucleic acids that have 90% sequence identity to SEQ ID NO:1.

Applicant urges that the specification teaches methods of assaying pesticidal activity on pg 8 and 29, and Examples 4 and 6-7 and one of skill in the art would readily be able to determine which nucleotide sequences have the desired pesticidal activity, without undue experimentation (response pg 14-15).

This is not found persuasive. Nucleic acids that have 90% identity to SEQ ID NO:1 would have up to 362 nucleotide substitutions, and thus could encode proteins with up to 362 amino acid or more substitutions; these proteins would have 69.9% identity to SEQ ID NO:2. The specification provides no guidance for which 362 amino acids to substitute. Thus, undue trial and error experimentation would be required to make the claimed nucleic acids.

Applicant urges that the quantity of experimentation required amounts to two steps - making a nucleic acid with 90% identity to SEQ ID NO:1 and assaying it for pesticidal activity, and that the experimentation required to practice the methods and make the plants is minimal and routine (response pg 16).

This is not found persuasive because the lack of guidance for which insertions, deletions and substitutions to make and the size of SEQ ID NO:1 (3621 nucleotides) means that undue trial and error experimentation would be required to make and analyze the claimed nucleic acids.

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Thus, many more than two steps would be required to find the nucleic acids that hybridizes to SEQ ID NO:1 or that has 90% identity to SEQ ID NO:1 AND that encodes a pesticidal protein.

4. Claims 1-3, 9-12, 17-19, 38, 42-43,46, 48-49, 52 and 54 remain rejected and claims 55-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 12 March 2003, as applied to claims 1-3, 9-12, 17-19, 38, 41-43,46-49 and 52-54.

Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

Applicant urges that recitation of at least 90% sequence identity is a very predictable structure (response pg 17).

This is not found persuasive. While nucleic acids that have 90% identity to SEQ ID NO:1 are predictable, nucleic acids that have 90% identity to SEQ ID NO:1 AND that encode pesticidal proteins are not. Applicant has not described nucleic acids that have 90% identity to SEQ ID NO:1 AND that encode pesticidal proteins.

Applicant urges that claims 42, 48 and 54 are drawn to nucleic acids that hybridize to SEQ ID NO:1, and that thus recitation provides a predictable structure of the claimed sequences (response pg 17).

This is not found persuasive. First, the hybridization conditions have not been completely described - the hybridization and wash times are not recited. Furthermore, even if they were recited, while nucleic acids that hybridize to SEQ ID NO:1 are predictable, nucleic acids that hybridize to SEQ ID NO:1 AND that encode pesticidal proteins are not. Applicant has not described nucleic acids that hybridize to SEQ ID NO:1 AND that encode pesticidal proteins.

Applicant urges that a description of a representative number of species does not require the description to provide support for each species encompassed by the genus. Applicant urges that the level of skill in the art would enable one to envision the claimed invention (response pg 17-18).

This is not found persuasive. Applicant has not described even one nucleic acid that hybridizes to SEQ ID NO:1 AND that encodes a pesticidal protein or that has 90% identity to SEQ ID NO:1 AND that encodes a pesticidal protein. The specification must describe the claimed invention.

Applicant urges that description of a genus can be by structure, formula, chemical name or physical properties and that a genus of DNAs can be described by recitation of a representative number of DNAs defined by a structural features common within the genus; the recitation of nucleic acids with 90% identity to SEQ ID NO:1 or hybridize to SEQ ID NO:1 is thus sufficient. Applicant urges that the recitation the sequences encode a pesticidal protein provides a functional characterization of the claimed sequences (response pg 18-19).

This is not found persuasive. The specification does not teach the structural features that distinguish nucleic acids that hybridize to SEQ ID NO:1 or have 90% identity to SEQ ID NO:1 AND that encodes a pesticidal protein from those that hybridize to SEQ ID NO:1 or have 90% identity to SEQ ID NO:1 and do not encode a pesticidal protein. Thus, the structural features common within the genus are not described.

Applicant urges that Example 14 of the Written Description Guidelines says that written description is satisfied by a claim of a protein with 95% identity to a given SEQ ID NO:., wherein the protein catalyzes a species reaction. Applicant urges that the instant claims fall satisfy the

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written description requirements because they claim nucleic acids with 90% identity to SEQ ID NO:1 and that encode a pesticidal protein (response pg 19).

This is not found persuasive the instant claims are drawn to a nucleic acid with 90% identity to SEQ ID NO:1. As discussed above, nucleic acids that have 90% identity to SEQ ID NO:1 would have up to 362 nucleotide substitutions, and thus could encode proteins with up to 362 amino acid or more substitutions; these proteins would have 69.9% identity to SEQ ID NO:2. 69.9% identity is quite different than 95% identity. Thus, the instant claims do not follow the model of example 14 of the Written description Guidelines.

5. Claims 42, 48 and 54 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

The rejection is repeated for the reasons of record as set forth in the Office action mailed 12 March 2003, as applied to claims 17-19, 41-42 and 47-54. Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

Claims 42, 48 and 54 are indefinite in their recitation of "stringent conditions". It is not clear what hybridization and wash conditions are considered stringent.

Applicant urges that the claims have been amended to recite particular hybridization and wash conditions (response pg 20).

This is not found persuasive because no hybridization and wash times are recited. Thus, the metes and bounds of the claimed nucleotide sequence are unclear.

Claim Rejections - 35 USC § 102

6. Claims 42, 48 and 54 remain rejected under 35 U.S.C. 102(b) as being anticipated by Michaels et al (1996, US Patent 5,554,534). The rejection is repeated for the reasons of record as set forth in the Office action mailed 12 March 2003. Applicant's arguments filed 29 May 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to recite hybridization and wash conditions (response pg 20-21).

This is not found persuasive because hybridization and wash times are not recited.

Applicant urges that SEQ ID NO:1 and the sequence of Michaels et al have a "query match" of only 70.8% and such sequences would not hybridize to one another under high stringency conditions (response pg 21).

This is not found persuasive because "query match" compares the similarity of the two sequences over the entire length of those sequences, while "local match" similarity only compares the regions with similarity. Because the sequence of Michaels et al is longer than the instant sequence, the "query match" similarity is less than the local match similarity. However, given the length of the regions with identity and because of the lack of recitation of hybridization and wash times, the sequence of Michaels et al would hybridize to the instant sequence, and thus anticipates the instant claims.

7. Claims 1-3, 9-12, 17-19, 38-41, 43-47 and 49-64 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid that has at least 90% identity to SEQ ID NO:1 or antisense molecules to that nucleic acid.

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8. Claims 50-51 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Claims 39-40 and 44-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
November 20, 2003



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600